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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,546	11/14/2003	Hans E. J. Hofland	020681-001710US	7974
20350 7590 02/12/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/12/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/713,546	<b>Applicant(s)</b> HOFLAND, HANS E. J.	
	<b>Examiner</b> Gollamudi S. Kishore, Ph.D	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims included in the prosecution are 1-11.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-4, 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The parent claims 1 and 8 recite only L-carnitine and L-carnitine is a specific compound. Therefore, claims 2-3 and 11 which recite 'propionyl-L-carnitine or acetyl-L-carnitine as L-carnitine of either claim 1 or 8 is inconsistent with the parent claims.

The use of a trade name in the claims is improper. The examiner suggests the incorporation of specific compound/composition in claim 4.

It should have been 'said L-carnitine derivative' in claim 7.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Stracher (4,866,040).

Stracher discloses liposomes containing amino carnitine and alkyl esters  
(abstract, columns 9-17).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by  
Keller (US 2002/0039595).

Keller discloses liposomes containing L-carnitine (Example 4).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by  
Keller (6,726,924).

Keller discloses liposomes containing L-carnitine (Example 4).

### ***Claim Rejections - 35 USC § 103***

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over  
Cavazza (5,747,536) in view of Keller (6,726,924) or Foldvari (5,993,851) individually or  
in combination.

Cavazza teaches the effectiveness of L-carnitine and its esters in the treatment  
of peripheral vascular diseases. The derivatives taught by Cavazza are acetyl L-  
carnitine and propionyl L-carnitine (abstract, columns 3-5 and claims).

What is lacking in Cavazza is the use of liposomes as the delivery vehicles for  
carnitines.

Keller discloses that liposomes are sustained release delivery vehicles for a

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variety of active agents including L-carnitine. According to Keller, liposomes increase the bioavailability of active agents when administered (col. 2, lines 13-65).

Foldvari while disclosing liposomal formulations containing various biologically active agents for topical delivery teaches that several studies showed that liposome encapsulation advantageously alters the pharmacokinetic fate of the drug after topical application (abstract, col. 1, lines 49-52) and that liposomes (containing active agent, PGE1) can be used to treat diseases including peripheral vascular disease (col. 27, lines 41-47).

The use of liposomes as the delivery vehicles for the compositions of Brevetti would have been obvious to one of ordinary skill in the art since Keller teaches that liposomes are sustained release delivery vehicles and increase the bioavailability of active agents and Foldvari teaches that the topical delivery of liposomes can be used to treat peripheral vascular diseases. Alternately to use liposomes for the encapsulation of L-carnitine or its esters for treatment of peripheral vascular diseases would have been obvious to one of ordinary skill in the art since L-carnitine and its esters are effective against this disease as taught by Brevetti. One of ordinary skill in the art would expect the advantages of liposomes in the delivery of L-carnitine.

8. Claims 1, 4-6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brevetti (4,968,719) in view of Keller (6,726,924) or Foldvari (5,993,851) individually or in combination or vice versa: that is, Keller and/or Foldvari in view of Brevetti.

Brevetti teaches L-carnitine's effectiveness for the treatment of peripheral

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vascular diseases (abstract, Examples and claims).

What is lacking in Brevetti is the use of liposomes as the delivery vehicles for carnitine.

Keller discloses that liposomes are sustained release delivery vehicles for a variety of active agents including L-carnitine. According to Keller, liposomes increase the bioavailability of active agents when administered (col. 2, lines 13-65).

Foldvari while disclosing liposomal formulations containing various biologically active agents for topical delivery teaches that several studies showed that liposome encapsulation advantageously alters the pharmacokinetic fate of the drug after topical application (abstract, col. 1, lines 49-52) and that liposomes (containing active agent, PGE1) can be used to treat diseases including peripheral vascular disease (col. 27, lines 41-47).

The use of liposomes as the delivery vehicles for the compositions of Brevetti would have been obvious to one of ordinary skill in the art since Keller teaches that liposomes are sustained release delivery vehicles and increase the bioavailability of active agents and Foldvari teaches that the topical delivery of liposomes can be used to treat peripheral vascular diseases. Alternately to encapsulate L-carnitine in liposomes for the treatment of peripheral vascular diseases would have been obvious to one of ordinary skill in the art since L-carnitine is effective against this disease as taught by Brevetti and topical application of liposomes is known for the treatment of peripheral vascular disease as taught by Foldvari or because liposomes are sustained release

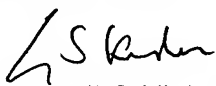
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vehicles as taught by Keller. One of ordinary skill in the art would expect the advantages of liposomes in the delivery of L-carnitine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK